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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/634,718	08/05/2003	Daniel Fred Ortwine	PC25319A	8926
28880	7590	09/27/2004	EXAMINER	
WARNER-LAMBERT COMPANY 2800 PLYMOUTH RD ANN ARBOR, MI 48105			HABTE, KAHSA Y	
			ART UNIT	PAPER NUMBER
			1624	

DATE MAILED: 09/27/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/634,718

Applicant(s)

ORTWINE, DANIEL FRED

Examiner

Kahsay Habte, Ph. D.

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-17 is/are pending in the application.
- 4a) Of the above claim(s) 4, 11 and 12 is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 1-3, 5-10 and 13-17 is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. ____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- ☒ Notice of References Cited (PTO-892)
- ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date 3/8/2004.
- ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. ____.
- ☐ Notice of Informal Patent Application (PTO-152)
- ☐ Other: ____.

DETAILED ACTION

Restriction/Election

1. Restriction to one of the following inventions is required under 35 U.S.C. 121:

- I. Claims 1-3 (in part), 5-8 (in part), 9-10 and 13-17 (in part), drawn to benzo[1,3]oxazin (i.e. $Y^2 = N$, $Y^3 = C$, $Y^4 = O$, and $U^5 = U^6 = U^8 = C$), classified in class 544, subclass 92.
- II. Claims 1-3 (in part), 5-8 (in part), 11-12 and 13-17 (in part), drawn to chromene (i.e. $Y^2 = Y^3 = C$, $Y^4 = O$, and $U^5 = U^6 = U^8 = C$), classified in class 549, subclass 399.
- III. Claims 1 (in part), 4, 5-7 (in part) and 13-17 (in part), drawn to others, classified in class 544, 546, subclass various.

The inventions are distinct, each from the other because of the following reasons: Groups I-III are directed to structurally dissimilar compounds such that the variable core created by the varying definitions of Y^2 , Y^3 , Y^4 , U^5 , U^6 or U^8 in Formula I do not belong to the same recognized class of chemical compounds in the art, and references anticipating one invention, would not render obvious the others. For example, Group I is drawn to a bicyclo ring namely benzo[1,3]oxazin ring (benzo ring fused to 1,3-oxazine) and is different from Groups II-III, since this is not present in Group II or Group III. Group II is drawn to chromene (i.e. benzofused to a six-membered ring with one oxygen, $Y^4 = O$) and is different from Group I or Group III. Group III is drawn to others (core structures that don't fall into Groups I-II, e.g. tricyclic rings, pyrido[1,3]oxazines, pyrido ring fused to a pyran, etc.) and is different from Groups I-II. Thus, separate

searches in the literature as well as in the U.S. Patent Classification System would be required. Each group's compounds are made and used independently of each other and could support separate patents. The compounds differ significantly in chemical structures. One skilled in the art would not consider such diverse structure equivalents of each other.

Because these inventions are distinct for the reasons given above and have acquired separate status in the art as shown by their different classification, restriction for examination purposes as indicated is proper.

During a telephone conversation with Mr. Claude Purchase on Sept. 22, 2004 a provisional election was made with traverse to prosecute the invention of Group I, claims 1-3, 5-10 and 13-17. Affirmation of this election must be made by applicant in replying to this Office action. Claims 4 and 11-12 are withdrawn from further consideration by the examiner, 37 CFR 1.142(b), as being drawn to a non-elected invention.

3. The claims are drawn to multiple inventions for reasons set forth in the restriction requirement. The claims are examined only to the extent that they read on the elected invention. Cancellation of the non-elected subject matter is recommended in response to this Office Action. Note that the composition claims and method claims recite claims 11-12 that are withdrawn.

Claim Rejections - 35 USC § 112

4. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claim 15 is rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for the treatment of arthritis namely osteoarthritis and rheumatoid arthritis, does not reasonably provide enablement for the treatment of other forms of arthritis e.g. systematic lupus erythematosus, juvenile arthritis, degenerative joint disease, gouty arthritis or psoriatic arthritis. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to use the invention commensurate in scope with these claims. There has been recited a treatment of arthritis in general that includes systematic lupus erythematosus, juvenile arthritis, degenerative joint disease or psoriatic arthritis (see page 71 of the specification for the definition of arthritis), but the specification is not enabled for such a scope.

According to a review article by Vincenti et al. {Arthritis Res. 2002; 4(3):157-64}, there is no mention of any treatment of arthritis such as systematic lupus erythematosus, juvenile arthritis, degenerative joint disease or psoriatic arthritis only arthritis mentioned are osteoarthritis and rheumatoid arthritis (see abstract).

Additionally, in a second article by Skotnicki JS et al., {Curr. Opin. Drug Discov. Devel. 2003 Sep; 6(5): 742-59}, there is no mention of any inhibition of MMP-13 for the treatment of systematic lupus erythematosus, juvenile arthritis, degenerative joint disease or psoriatic arthritis only arthritis mentioned are osteoarthritis and rheumatoid

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arthritis. It is up to applicants to link MMP-13 to the treatment of arthritis selected from systematic lupus erythematosus, juvenile arthritis, degenerative joint disease or psoriatic arthritis. These operate via very different mechanisms e.g. gouty arthritis arises from an overproduction of uric acid, or a reduced ability of the kidney to eliminate uric acid so that uric acid sodium salt builds up in joints or unknown mechanism (e.g. SLE).

Claim Rejections - 35 USC § 112

5. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-3, 5-10 and 13-17 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention:

a. Claim 1 and claims dependent thereon are rejected because the term "substituted" is indefinite. In the absence of the specific moieties intended to effectuate modification by the "substitution" or attachment to the chemical core claimed, the term "substituted" renders the claims in which it appears indefinite in all occurrences wherein applicants fails to articulate by chemical name, structural formula or sufficiently distinct functional language, the particular moieties applicants regards as those which will facilitate substitution, requisite to identifying the composition of matter claimed.

b. In claim 1 or elsewhere in the claim, the phrase "cycloalkyl-(C₁-C₈ alkylenyl);phenyl-(C₁-C₈ alkylenyl)...Naphthyl-(C₁-C₈ alkylenyl)" is not clear. What does the phrase "phenyl-(C₁-C₈ alkylenyl)" indicate? Is it for example indicating phenyl-(CH₂)_m-? If so, it should read as "phenyl-(C₁-C₈ alkylene" or "phenyl(C₁-C₈ alkyl)". Does it indicate a phenyl group attached to alkenyl (e.g. phenyl-(C=C-C₇)? If so, it should read as "phenyl-(C₂-C₈ alkenyl)".

c. In claim 10 (page 135) the nomenclature of the two species "benzo[1,3]oxazin-4-one" is incorrect. It should read as "benzo[1,3]oxazin-4-one".

Conclusion

6. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Kahsay Habte, Ph. D. whose telephone number is (571) 272-0667. The examiner can normally be reached on M-F (9.00AM- 5:30PM).

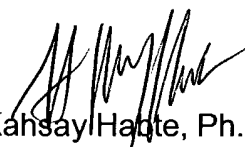
If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Mukund Shah can be reached on (571) 272-0674, if there is no reply within 24 hours, James Wilson (Acting SPE) can be reached at (571) 272-0661. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR.


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Status information for unpublished applications is available through Private PAIR only.

For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



Kahsay Hapte, Ph. D.
Examiner
Art Unit 1624



Mark L. Berch
Primary Examiner
Art Unit 1624

KH
September 23, 2004